Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	Primary Thromboprophylaxis in Patients With Malignancy and Central Venous Catheters: a Randomized Controlled Trial
Protocole ID	TRIM-Line 3698
ClinicalTrials.gov ID	NCT05029063
Type(s) de cancer	Contrôle des symptômes
Type étude	Support
Médicament	Rivaroxaban 10 MG
Institution	CISSS DE CHAUDIERE-APPALACHES HOTEL-DIEU DE LEVIS 143 rue Wolfe, Lévis, QC, G6V 3Z1
Ville	
Investigateur principal	Dr Frédéric Larose
Coordonnateur	Pierre Bédard 418-835-7121
Statut	Actif en recrutement
Date d'activation	16-11-2023
But étude	The purpose of the full trial is to determine the efficacy and safety of prophylactic dose rivaroxaban to prevent VTE among cancer patients with CVC.
Critères d'éligibilité	• Patients 18 years of age or older with a new or existing diagnosis of cancer and a CVC inserted in the last 72 hours.

Critères d'exclusion	• CVC in place for >72 hours
	• Patient requires anticoagulation for other indications
	• Concomitant use of dual antiplatelet therapy
	• Major bleeding event in the last 4 weeks
	• Patients receiving concomitant systemic treatment with strong inhibitors of both CYP 3A4 and P-gp (such as cobicistat, ketoconazole, itraconazole, posaconazole, or ritonavir).
	• Known pregnancy or plan to become pregnant in next 3 months
	• Severe renal insufficiency (Creatinine clearance <30 mL/min (defined by Cockcroft-Gault) in the previous 3 months
	• Documented severe liver disease (e.g., acute clinical hepatitis, chronic active hepatitis or cirrhosis) in the previous 3 months
	• Known thrombocytopenia (platelet count < 50x 109/L) in the previous 3 months
	• Known allergy to rivaroxaban
	• Life expectancy <3 months
	• History of condition at increased bleeding risk including, but not limited to:
	  • cerebral infarction (hemorrhagic or ischemic), active peptic ulcer disease with recent bleeding, spontaneous or acquired impairment of hemostasis in the past 4 weeks.
	  • Chronic hemorrhagic disorder
	• Primary malignancy diagnosis of basal cell or squamous cell carcinoma of the skin only
	• Refused or unable to obtain consent